REMARKS

Claims 1 to 4, 6, 7, 9 to 12, 14 and 15 as set forth in Appendix I of this paper are now pending in this case. Claims 6 and 7 have been amended as indicated in the listing of the claims set forth in Appendix I of this paper.

The Examiner rejected Claims 6 and 7 under 35 U.S.C. §112, ¶2, as being indefinite for lack of proper antecedent basis for the expression "the grapevine plant" in line 3 of Claim 6, and the expression "the plant" in line 3 of Claim 7. Applicants' amendment obviates the respective issues. It is therefore respectfully requested that the rejection be withdrawn. Favorable action is solicited.

The Examiner rejected Claims 6, 7 and 15 under 35 U.S.C. §102(b) as being anticipated by the teaching of ***Cervelle et al.*** **(US 4,460,578)**. It is respectfully urged that the Examiner's respective position is in error.

Anticipation under Section 102 can be found only if a reference shows exactly what is claimed, ie. all material elements of the invention as claimed must be found in one prior art source,[2] the elements must be shown in the reference in as much detail as is contained in the claim,[3] and the elements must be shown in the reference in the part-to-part relationship which is set forth in the claim.[4] The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103.[5] However, the fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.[6] *"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'"*[7]

Also, while the patentability of a product does not depend on its method of production,[8] the structure which is implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined

2) Cf. *In re Marshall*, 577 F.2d 301, 198 USPQ 344 (CCPA 1978); *In re Kalm*, 378 F.2d 959, 154 USPQ 10 (CCPA 1967).

3) Cf. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989).

4) Cf. *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984).

5) *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995). See also *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

6) *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981).

7) *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

8) *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product.[9] To establish a *prima facie* case of anticipation or obviousness, and to shift the burden of proof to the applicant, the examiner has to provide a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process.[10]

Considering the foregoing standards developed by the Courts, the reference relied upon by the Examiner fails to anticipate the subject matter of applicants' claims, and the Examiner's respective arguments are deemed to be based on error.

As already pointed out by applicants in their previous paper,[11] the teaching of ***Cervelle et al.*** relates to a total extract of *Lespedeza capitata* Michaux, a leguminous plant,[12] and the authors inter alia explain that "*Lespedeza hedysaroids* ... is a different species from *Lespedeza capitata*" and that chromatographic tests have shown that the flavonoids of the *Lespedeza hedysaroids* extract were different from those of *Lespedeza capitata*.[13]

In contrast thereto, applicants' Claim 6 pertains to an extract, juice, wine or press cake comprising flavonoids and other phenolic constituents which is, inter alia, required to be "*obtained from grapes of a grapevine plant of a red grapevine variety.*" Considering the teaching of ***Cervelle et al.*** that the flavonoids of two different *Lespedeza* species differ from one another, there is clearly no reasonable basis to assert that the flavonoids or other phenolic constituents which are present in a product obtained from *grapes of a grapevine plant of a red grapevine variety* are identical with the flavonoids which are present in

- the total extract of *Lespedeza capitata* Michaux, or
- the extract of *Lespedeza hedysaroids*,

which are mentioned by ***Cervelle et al.*** The Examiner argued: "*In a claim to a composition / product (extract) the components thereof are limitations, not steps as to how the extract is obtained.*"[14] This argument is, however, clearly in error because, as noted in the foregoing, it is well settled that process provisions which impart distinctive characteristics to a product cannot be disregarded.

Moreover, the Examiner failed to provide a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art. On the one hand, the Examiner disregarded the requirement of Claim 6 that the extract, juice, wine or press cake be "*obtained from grapes of a grapevine plant of a red grapevine variety,*" i.e. a requirement which, in itself, imparts distinctive

9) See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979).

10) *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

11) Reply dated June 19, 2006; the respective paper is herewith incorporated by reference.

12) Cf. e.g. col. 1, indicated lines 6 to 15, of ***US 4,460,578***.

13) Cf. col. 3, indicated lines 1 to 5, of ***US 4,460,578***.

14) Office action page 2, lines 10 to 12.

characteristics to the product. On the other hand, the Examiner disregarded the requirement of Claim 6 that the said grapevine plant have been treated in a particular manner such that the content of flavonoids and other phenolic constituents of the grapevine is increased and qualitatively modified. As explained in particular on page 5, indicated line 8, to page 6, indicated line 6, of the application and illustrated in applicants' Figure 1, compounds of applicants' formula (I) which are employed in the particular pre-treatment which is required in accordance with Claim 6 inhibit certain enzymes involved in the synthesis of, e.g., catechin. The pre-treatment procedure which is required in accordance with applicants' Claim 6, therefore, also clearly imparts distinctive structural characteristics to the final product. Notably, the extract addressed in the ***Cervelle et al.*** reference is described to consist essentially of flavonoids, *catechic tannins* and phenol acids.[15]

The Examiner's position that "*claim 6 is to an extract comprising flavonoids and other phenolic compounds rather than to a method of obtaining an extract,*" and that "*Cervelle's extract meets the limitations of the claimed extract*"[16] is in light of the foregoing not deemed to be well taken.

Essentially the same applies where the subject matter of Claims 7 and 15 is concerned. Claim 7 refers to certain compositions comprising a certain plant, or a part or product thereof, wherein

- the plant is selected from grapevines, cherries, plums, sloes, blueberries, strawberries, citrus fruit, pawpaw, red cabbage, broccoli, Brussels sprouts, kale, carrots, parsley, celery/celeriac, onions, garlic, tea, coffee, cacao, maté, hops, soya, oilseed rape, oats, wheat, rye, *Aronia melanocarpa* and *Ginkgo biloba*, and
- the product is selected from juices, teas, extracts, fermentation products and fermentation residues.

Additionally, and corresponding to Claim 6, Claim 7 requires that the plant have been pre-treated with a compound of applicants' formula (I). The Examiner again argued "*in a claim to a composition, information recited therein as to how the product was prepared (e.g. wherein plant has been treated with acylcyclohexanedione) adds no patentable weight to the composition.*"[17] This argument is deemed to be in error because, as noted in the foregoing, it is well settled that process provisions which impart distinctive characteristics to a product cannot be disregarded. The foregoing remarks also show that the nature of the plant referenced in applicants' claim, as well as the required pre-treatment of the referenced plant, impart distinctive characteristics to the product claimed by applicants.

At least for the reasons set forth above, and in light of applicants' previous remarks,[11] it is respectfully urged that the teaching of ***Cervelle et al.*** cannot be deemed to anticipate the subject matter of applicants' claims, and that the Examiner has not met the burden to establish a *prima facie* case

15) E.g. col. 3, indicated lines 6 to 12, and col. 5, indicated lines 46 to 53, of ***US 4,460,578.***

16) Office action page 2, lines 8 to 10.

17) Office action page 2, lines 15 to 18.

of anticipation. It is therefore respectfully requested that the rejection be withdrawn. Favorable action is solicited.

Additionally, the Examiner rejected Claims 1, 2, 4, and 10 to 12 under 35 U.S.C. §112, ¶1, asserting that applicants' description of the subject matter specified in those claims is insufficient to enable a person of ordinary skill in the art to make and/or use the claimed invention for increasing and qualitatively modifying the content of flavonoids and phenolic constituents in a plant other than grapes.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied.[18] Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation.[18][19] The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation.[18][20] The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue.[21]

Compliance with the enablement requirement of 35 U.S.C. 112 does not turn on whether an example is disclosed. An applicant need not have actually reduced the invention to practice prior to filing.[22] The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation.[23] As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement is satisfied.[24]

In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention.[25] Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that

18) *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

19) See also *United States v. Telectronics, Inc.*,857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).

20) *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), aff'd. sub nom., *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985).

21) *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

22) *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987).

23) *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

24) *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

25) *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

basis.[26] As stated by the court:[27] "*it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.*"

The Examiner argued:[28] "*Working examples are to grapes.*" However, as noted in the foregoing, compliance with the enablement requirement of 35 U.S.C. 112 does not turn on whether an example is disclosed. The question is whether a person having ordinary skill in the art who has the application before him is enabled to make and/or use applicants' method with plants other than grapes.

The Examiner also argued:[29] "*The chemistry between the flavonoids of fruits / vegetables and the acylcylohexanedione compounds* may *differ and therefore* may or may not *increase and qualitatively modify the content of flavonoids and phenolics constituents of all vegetables and fruits claimed.*" Considering the foregoing standards developed by the Courts, it is respectfully urged that the Examiner's argument is not deemed to be acceptable evidence or reasoning in support of the Examiner's rejection. Applicants' method is not based on the chemistry between the flavonoids and the acylcyclohexanedione compounds. Rather, as pointed out by applicants:[30]

> *It can be considered as proven that prohexadione-calcium, trinexapac-ethyl and other acylcyclohexanediones inhibit 2-oxoglutaric-acid dependent hydroxylases which are of importance in the metabolism of phenolic substances. These hydroxylases are primary chalcone syntetase (CHS) and flavone 3-hydroxylase (F3H) ... [S]ince CHS and F3H are ... being inhibited, these flavoid end products [e.g. catechin, cyanidin] cannot be formed, and the result is an increased production of luteoliflavan, eriodictyol and other phenols (Figure 1).*

The Examiner's position that differences *may* exists and that any such differences *may or may not* cause a different result is also not deemed to be acceptable evidence or reasoning in support of the Examiner's rejection. As such, it is respectfully urged that the Examiner has not met the burden to establish that a person of ordinary skill in the pertinent art would reasonably question that the experiments which are described in the application are representative of the scope of applicants' claims. Accordingly, there should be no need for applicants "*to go to the trouble and expense of supporting his presumptively accurate disclosure.*"[27]

Nonetheless, applicants herewith enclose a Declaration of Dr. Rademacher which describes the impact of a treatment with prohexadione-calcium[31] on the content of flavonoids and phenolic con-

---

26) *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

27) Ibid. 439 F.2d at 224, 169 USPQ at 370.

28) Office action page 3, indicated lines 19 and 20.

29) Office action page 3, indicated lines 20 to 23 (emphasis added).

30) Cf. page 6, indicated lines 1 to 17, of the application.

31) Applicants' formula II, cf. page 6, indicated lines 35 to 45, of the application.

stituents in hop plants. As noted by Dr. Rademacher in the Declaration, the results which were obtained in the described investigations are in line which results obtained in apple shoots, a result which is confirmed by a publication of ***Roemmelt et al.***[32] Additionally, applicants' herewith enclose copies of:

a) ***S. Roemmelt et al.***, Acta Hort. 590, pp. 477-484, ISHS 2002; and

b) ***H. Halbwirth et al.***, Z. Naturforsch. 58c, 765-770 (2003).

Publication (a) shows that prohexadione-Ca induces changes in the spectrum of flavonoids in young leaves of apple and or pear.[33] In particular, eriodictyol-7-glucoside and luteoliflavan, which normally do not occur in these plants, can be detected in leaves of treated plants. Publication (b) gives further insight into the biochemical interference of prohexadione-Ca and related compounds with flavonoid biosynthesis. Table 1 on page 769 of the reference indicates a number of plant species (grapevine, strawberry, kiwi, peach, rose, cranberry, elder, plum and cherry) for which biochemical evidence is available that prohexadione-Ca leads to significant changes in the spectrum of flavonoids. Although the additional art was published only after the earliest effective filing date, the results which are reported in the respective publications should suffice to assuage the Examiner's concerns that the effect of applicants' method ***may or may not*** result when the plant which is treated in accordance with applicants' method differs from the plant which was employed in applicants' illustrative example.

In light of the foregoing and the attached it is respectfully requested that the rejection of Claims Claims 1, 2, 4, and 10 to 12 under 35 U.S.C. §112, ¶1, be withdrawn. Favorable action is solicited.

32) *Phytochemisty 64*, 2003, 709 to 716 (*copy enclosed*). Figure 7 of the reference proposes the points of inhibition by prohexadione-Ca of flavonoide metabolism. Blocking FHT (flavanone-3-hydroxylase) "forces" the plant to produce new types of flavonoids, such as eriodictyol-7-glucoside and luteoliflavan. This biochemical pathway is typical for most plant species, as e.g. supported by *B. Winkel*, The Science of Flavonoids, edited by Erich Grothe, Springer, Chapter 3, The Biosynthesis of Flavonoids, in particular page 72 (*copy enclosed*).

33) Cf., e.g., abstract and page 483, tables 2 and 3.